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ANNE S DOLLARD ESQ
CHIRON CORPORATION
INTELLECTUAL PROPERTY R440
PO BOX 8097
EMERYVILLE CA 94662-8097

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/475,704	BARNETT ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1633	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claims 1-66 are pending and under consideration in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 24-43, 49-60, and 62-66, drawn to an expression cassette comprising a polynucleotide sequence encoding a polypeptide including an HIV Gag polypeptide, wherein the polynucleotide sequence encoding said Gag polypeptide comprises a sequence having at least 90% sequence identity to the sequence presented as nucleotides 844-903 of Figure 1 (SEQ ID NO: 1), a recombinant expression system for use in a selected host cell, comprising, an expression cassette of claim 1, a composition for generating an immunological response, comprising an expression cassette of claim 1, a method of generating an immune response in a subject, comprising introducing into cells of said subject an expression cassette of claim 1, under conditions that permit the expression of said polynucleotide and production of said polypeptide, thereby eliciting an immune response to said polypeptide, a method of claim 49, wherein said expression cassette is introduced using a gene delivery vector, classified in class 514,

subclass 44, classified in class 435, subclass 320.1, class 536, subclass 23.1, class 424, 184.1+.

II. Claims 1, 24-43, 49-60, and 62-66, drawn to an expression cassette comprising a polynucleotide sequence encoding a polypeptide including an HIV Gag polypeptide, wherein the polynucleotide sequence encoding said Gag polypeptide comprises a sequence having at least 90% sequence identity to the sequence presented as nucleotides 841-900 of Figure 2 (SEQ ID NO: 2), a recombinant expression system for use in a selected host cell, comprising, an expression cassette of claim 1, a composition for generating an immunological response, comprising an expression cassette of claim 1, a method of generating an immune response in a subject, comprising introducing into cells of said subject an expression cassette of claim 1, under conditions that permit the expression of said polynucleotide and production of said polypeptide, thereby eliciting an immune response to said polypeptide, a method of claim 49, wherein said expression cassette is introduced using a gene delivery vector, classified in class 514, subclass 44, classified in class 435, subclass 320.1, class 536, subclass 23.1, class 424, 184.1+.

III. Claims 2-9, drawn to an expression cassette comprising a polynucleotide sequence encoding a polypeptide including an HIV Gag polypeptide, wherein the polynucleotide sequence encoding said Gag polypeptide comprises a sequence having at least 90% sequence identity to the sequence presented as Figure 1 (SEQ ID NO: 3), expression cassette of claim 2, wherein said polynucleotide sequence

further includes a polynucleotide sequence encoding a polypeptide including and HIV protease polypeptide, expression cassette of claim 2, wherein said polynucleotide sequence further includes a polynucleotide sequence encoding a polypeptide including and HIV polymerase polypeptide, the expression cassette of claim 2, wherein said polynucleotide sequence further includes a polynucleotide sequence encoding an HIV polymerase polypeptide is modified by deletions of coding regions corresponding to reverse transcriptase and integrase, the expression vector of claim 9, wherein said polynucleotide sequence preserves T-helper cell or CTL epitopes, classified in class 435, subclass 320.1, class 536, subclass 23.1.

IV. Claims 2, 4, and 6-9, drawn to an expression cassette comprising a polynucleotide sequence encoding a polypeptide including an HIV Gag polypeptide, wherein the polynucleotide sequence encoding said Gag polypeptide comprises a sequence having at least 90% sequence identity to the sequence presented as Figure 2 (SEQ ID NO: 4), expression cassette of claim 2, wherein said polynucleotide sequence further includes a polynucleotide sequence encoding a polypeptide including and HIV protease polypeptide, expression cassette of claim 2, wherein said polynucleotide sequence further includes a polynucleotide sequence encoding a polypeptide including and HIV polymerase polypeptide, the expression cassette of claim 2, wherein said polynucleotide sequence further includes a polynucleotide sequence encoding an HIV polymerase polypeptide is modified by deletions of coding regions corresponding to reverse transcriptase and integrase, the

expression vector of claim 9, wherein said polynucleotide sequence preserves T-helper cell or CTL epitopes, classified in class 435, subclass 320.1, class 536, subclass 23.1.

V. Claims 11 and 44-46, drawn to an expression cassette comprising a polynucleotide sequence encoding a polypeptide including an HIV Env polypeptide, wherein the polynucleotide sequence encoding said Env polypeptide comprises a sequence having at least 90% sequence identity to the sequence presented as nucleotides 1213-1353 of Figure 3 (SEQ ID NO: 5), drawn to a composition for generating an immunological response, comprising an expression cassette of claim 11, a composition for generating an immunological response, comprising an expression cassette of claim 11, further comprising an Env polypeptide, a composition for generating an immunological response, comprising an expression cassette of claim 11, further comprising an adjuvant, classified in class 435, subclass 320.1, class 536, subclass 23.1.

VI. Claim 12, the expression cassette of claim 11 drawn to an expression cassette, wherein the polynucleotide sequence encoding said Env polypeptide further comprises a sequence having at least 90% sequence identity to the sequence presented as nucleotides 82-1512 of Figure 3 (SEQ ID NO: 6), class 435, subclass 320.1, class 536, subclass 23.1.

VII. Claim 13, the expression cassette of claim 11, wherein the polynucleotide sequence encoding said Env polypeptide further comprises a sequence having at least 90% sequence identity to the sequence presented as nucleotides 82-2025 of

Figure 3 (SEQ ID NO: 7), classified in class 435, subclass 320.1, class 536, subclass 23.1.

VIII. Claim 14, the expression cassette of claim 11, wherein the polynucleotide sequence encoding said Env polypeptide further comprises a sequence having at least 90% sequence identity to the sequence presented as nucleotides 82-2547 of Figure 3 (SEQ ID NO: 8), classified in class 435, subclass 320.1, class 536, subclass 23.1.

IX. Claims 15 and 23, drawn to the expression cassette of claim 11, wherein the polynucleotide sequence encoding said Env polypeptide further comprises a sequence having at least 90% sequence identity to the sequence presented as nucleotides 1-2547 of Figure 3 (SEQ ID NO: 9), an expression cassette, comprising a polynucleotide sequence encoding a polypeptide including an HIV Env polypeptide, wherein the polynucleotide sequence encoding said Env polypeptide consists of a sequence having the sequence presented as Figure 3 (SEQ ID NO:9), classified in class 435, subclass 320.1, class 536, subclass 23.1.

X. Claim 16, drawn to an expression cassette comprising a polynucleotide sequence encoding a polypeptide including an HIV Env polypeptide, wherein the polynucleotide sequence encoding said Env polypeptide comprises a sequence having at least 90% sequence identity to the sequence presented as nucleotides 1513-2547 of Figure 3 (SEQ ID NO: 10), classified in class 435, subclass 320.1, class 536, subclass 23.1.

XI. Claim 17, drawn to an expression cassette comprising a polynucleotide sequence encoding a polypeptide including an HIV Env polypeptide, wherein the polynucleotide sequence encoding said Env polypeptide comprises a sequence having at least 90% sequence identity to the sequence presented as nucleotides 1210-1353 of Figure 4 (SEQ ID NO: 11), class 435, subclass 320.1, class 536, subclass 23.1.

XII. Claim 18, drawn to the expression cassette of claim 17, wherein the polynucleotide sequence encoding said Env polypeptide further comprises a sequence having at least 90% sequence identity to the sequence presented as nucleotides 73-1059 of Figure 4 (SEQ ID NO: 12), class 435, subclass 320.1, class 536, subclass 23.1.

XIII. Claim 19, drawn to the expression cassette of claim 17, wherein the polynucleotide sequence encoding said Env polypeptide further comprises a sequence having at least 90% sequence identity to the sequence presented as nucleotides 73-2022 of Figure 4 (SEQ ID NO: 13), classified in class 435, subclass 320.1, class 536, subclass 23.1.

XIV. Claim 20, drawn to the expression cassette of claim 17, wherein the polynucleotide sequence encoding said Env polypeptide further comprises a sequence having at least 90% sequence identity to the sequence presented as nucleotides 73-2565 of Figure 4 (SEQ ID NO: 14), classified in class 435, subclass 320.1, class 536, subclass 23.1.

XV. Claims 21 and 23, drawn to the expression cassette of claim 17, wherein the polynucleotide sequence encoding said Env polypeptide further comprises a sequence having at least 90% sequence identity to the sequence presented as nucleotides 1-2565 of Figure 4 (SEQ ID NO: 15), an expression cassette, comprising a polynucleotide sequence encoding a polypeptide including an HIV Env polypeptide, wherein the polynucleotide sequence encoding said Env polypeptide consists of a sequence having the sequence presented as Figure 4 (SEQ ID NO:15), classified in class 435, subclass 320.1, class 536, subclass 23.1.

XVI. Claim 22, drawn to an expression cassette, comprising a polynucleotide sequence encoding a polypeptide including an HIV Env polypeptide, wherein the polynucleotide sequence encoding said Env polypeptide comprises a sequence having at least 90% sequence identity to the sequence presented as nucleotides 1510-2565 of Figure 4 (SEQ ID NO: 16), classified in class 435, subclass 320.1, class 536, subclass 23.1.

XVII. Claims 47 and 48, drawn to a composition of either claim 44 or 45 further comprising an expression cassette of claim 1, further comprising a Gag polypeptide, classified in class 424, 184.1+, class 435, subclass 320.1, class 536, subclass 23.1.

XVIII. Claim 61, drawn to a method of generating an immune response in a subject, comprising: providing an expression cassette of claim 1, expressing said polypeptide in a suitable host cell, isolating said polypeptide, and administering

said polypeptide to the subject in an amount sufficient to elicit and immune response, classified in class 424, subclass 184.1+.

The inventions are distinct, each from the other because:

Inventions I and II-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polynucleotide sequence of invention I encodes nucleotides 844-903 of Figure 1 (SEQ ID NO: 1). The polynucleotide sequences of inventions II-XVI encode different nucleotide sequences (SEQ ID NO: 2-16) than in invention I (SEQ ID NO: 1). Invention I requires different materials and the process for making the composition than in inventions II-XVI.

Inventions II and I, III-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polynucleotide sequence of invention II encodes nucleotides 841-900 of Figure 2 (SEQ ID NO: 2). The polynucleotide sequences of inventions I, III-XVI (SEQ ID NO: 1, 3-16) encode different nucleotide sequences than in invention II. Invention II requires different materials and the process for making the composition than in inventions I, III-XVI.

Inventions V and I-IV, VI-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polynucleotide sequence of invention V encodes nucleotide 1213-1353 of Figure 3 (SEQ ID

NO: 5). The polynucleotide sequences of inventions I-IV, VI-XVI encode different nucleotide sequences (SEQ ID NO: 1-4, 6-16) than in invention V. Invention V requires different materials and the process for making the composition than in inventions I-IV, and VI-XVI.

Inventions III and IV-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are directed to different polynucleotide sequences. Each invention requires different material and the process for making the composition for each polynucleotide sequence claimed.

Inventions I, II, V and XVII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the composition of each invention I, II and V can be used without the particulars of the subcombination in invention XVII as claimed for patentability for generating an immune response in a subject. The subcombination has separate utility such as use in an *in vitro* diagnostic test.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because each of the methods of inventions I-II, V, and XVIII constitutes patentably distinct inventions for the following reasons: Each of the inventions is directed to different goals

and comprises materially distinct steps, wherein each of the compositions in each invention is structurally distinct and/or generates distinct mechanisms and functional effects as indicated above. The scope of each of the cited inventions encompasses an employed method, which generates distinct function(s) and effect(s), and furthermore does not necessarily overlap with that of another invention. Furthermore, none of the method steps cited in inventions I-II, V use polypeptide therapy as claimed in invention XVIII. Each of the inventions I-II, V and XVIII comprises materially distinct steps, and/or generates different functions and effects, and thus, is not required for use with one another.

This application contains claims directed to the following patentably distinct species of the claimed invention: mammalian cell specifically recited in Markush Group of claim 29, insect cell specifically recited in Markush Group of claim 32, bacterial cell in claim 33, yeast cell in claim 34, plant cell in claim 35, antigen presenting cell specifically recited in Markush Group of in claim 37, primary cell in claim 38, immortalized cell in claim 39, and tumor-derived cell in claim 40.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 27 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Should applicant elect an invention encompassing the Markush Group of claim 29, a further restriction of species is required. Claim 28 is generic to a plurality of disclosed patentably distinct species in claim 29 comprising BHK, VERO, HT1080, 293, RD, COS-7 AND CHO cells. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant elect an invention encompassing the Markush Group of claim 32, a further restriction of species is required. Claim 31 is generic to a plurality of disclosed patentably distinct species in claim 32 comprising Tn5 or Sf9 insect cells. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant elect an invention encompassing the Markush Group of claim 37, a further restriction of species is required. Claim 36 is generic to a plurality of disclosed

patentably distinct species in claim 37 comprising macrophage, monocytes, dendritic cells, B-cells, T-cells, stem cells, and progenitor cells. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Furthermore, if applicant elects Invention I or II, applicant must further elect from Claim 26, which is generic to a plurality of disclosed patentably distinct species comprising CMV, CMV+intron A, SV40, RSV, HIV-Ltr, MMLV-ltr, and metallothionein. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If applicant elects from Inventions XVII, XVIII, applicant must further elect from claim 1 either SEQ ID NO: 1 or SEQ ID NO: 2. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from claim 1, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated s proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Tracey Johnson whose telephone number is (703) 305-2982.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on M-F, (730-400 EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DAVE T. NGUYEN
PRIMARY EXAMINER

Brian Whiteman

Patent Examiner

April 16, 2001